REMARKS

The Office Action mailed on March 30, 2009 has been reviewed and the comments of the Examiner carefully considered. Claims 9, 10, 13 and 17 are pending. Claim 13 has been canceled. Claim 17 has been amended. New claims 18-22 have been added. Support for these amendments may be found, for example, at page 4, lines 6-10 of the specification. No new matter has been added by way of these amendments.

Rejections under 35 U.S.C. § 112

Claim 13 was rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants have herein canceled claim 13, rendering this rejection moot. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. § 102

Claims 9, 13 and 17 were rejected under 35 U.S.C. § 102(b) as anticipated by Tunc (US 3,800,797). Regarding independent claim 17, the Examiner alleged that Tunc discloses a barrier film which has utility in connection with absorbent products of various applications that include "dressings", and which comprises a film of sulfated alkali cellulose ether resin, wherein the sulfated alkali cellulose ether of the resin may be selected as sodium hydroxyethyl cellulose sulfate – thereby anticipating instant claim 17 when the instantly claimed wound dressing comprises the sulfated hydroxyethyl cellulose.

Applicants respectfully disagree and continue to assert that the claims are not anticipated for the reasons stated in the reply filed October 21, 2008.

For the purposes of furthering prosecution and further clarifying the scope of the instant invention only, and without any admission as to the propriety of this rejection, Applicants have also herein amended claim 17 as follows:

> "A wound dressing comprising a synthetic sulfated polysaccharide, wherein the sulfated polysaccharide is selected from the group consisting of sulfated hydroxyethyl cellulose, sulfated carboxymethyl cellulose and sulfated oxidized regenerated cellulose, ***said synthetic sulfated polysaccharide being present in an amount sufficient to bind matrix metalloproteinases***; and wherein at least one sulfate group on each saccharide residue of said synthetic sulfated polysaccharide was converted from a hydroxyl group" (emphasis added).

As set forth in MPEP § 2133, a rejection under 35 U.S.C. § 102(b) requires that the claimed invention was patented in this or a foreign country more than one year prior to the date of application for patent in the United States. Anticipation exists only when the cited reference discloses all the elements, features, or limitations. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Thus, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

Applicants respectfully submit that Tunc does not teach, suggest, or otherwise disclose all the elements, features, or limitations of applicants' as-amended claim 17. More specifically, Tunc does not disclose or suggest a wound dressing comprising a synthetic sulfated polysaccharide present in an amount sufficient to bind matrix metalloproteinases wherein at least one sulfate group on each saccharide residue of the polysaccharide was converted from a hydroxyl group. Rather, Tunc teaches away from the degree of sulfation in the instant invention:

> "It has further been discovered that modifying the D.S. ["degree of sulfate substitution"; *see, e.g.*, col. 2, line 1] of these resins, the salt resistances and water dispersability of the films can be modified to suit the particular purposes of this invention, *i e.*, films which will adequately provide a barrier for body fluids for a suitable length of time and which may be flushed away in a water closet. Specifically, ***by lowering the degree of sulfation***, the barrier films of this invention become more resistant to salt solutions in that they retain their integrity after being subjected to these solutions for longer periods of time and that they exhibit higher tensile strengths when subjected to a given salt concentration for a given period of time. In general, if the D.S. is maintained,

> at below about 0.4 an adequately salt resistant film results. Preferably, ***the D.S. should be maintained at below about 0.3 and more preferably below 0.2.***"
> (*see, e.g.*, col. 3, line 59 – col. 4, line 8 of US 3,800,797; emphasis added).

Thus, the properties of the devices of Tunc – *i.e.*, retaining tensile strength in salt solutions such as body fluids while readily dispersing in tap water – are a function of the degree of sulfate substitution, which expresses the average number of sulfate groups per anhydroglucose unit of the cellulosic ether, and increasing the degree of sulfate substitution of a particular resin of Tunc will result in films exhibiting "increasing dispersibility in water and decreasing strength in salt solutions" (*see, e.g.*, col. 1, line 63 – col. 2, line 6 of US 3,800,797).

In contrast, the degree of sulfate substitution in the instant invention is at least a degree of magnitude greater than that of Tunc: "at least 1 hydroxyl group, on average, on each saccharide residue has been converted to sulfate groups, and most preferably from 3 to 4 hydroxyl groups on each saccharide residue have been so converted" (*see, e.g.*, page 4, lines 6-10 of the instant Specification). It is this degree of sulfate substitution of the synthetic sulfated polysaccharides, and the presence of a sufficient amount of the synthetic sulfated polysaccharides of the instant invention in the claimed wound dressings that provide unexpected advantages as wound healing materials, and further exhibit anticoagulant properties. More specifically, it is the degree of sulfate substitution of "at least 1" in the instant invention that provides the surprising and unexpected ability to exceptionally bind matrix metalloproteinases that have been implicated in a number of medical conditions, including chronic wounds, and the surprising and unexpected anticoagulant properties (*see, e.g.*, page 5, lines 15-26; page 6, lines 10-17). Such properties are the exact opposite of the haemostatic properties well known for oxidized regenerated cellulose itself.

Therefore, because claim 17 has been herein amended to include the limitation of "at least one" sulfate group on each saccharide residue of said synthetic sulfated polysaccharide was converted from a hydroxyl group, and because Tunc does not teach, suggest, or otherwise disclose this limitation – and indeed, teaches away from this limitation – applicants respectfully reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b). Further, applicants submit that claims 9-10 and 18-22 are thereby allowable as written as depending from an allowable independent claim.

Rejections under 35 U.S.C. § 103

Claims 9, 10, 13 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tunc, in view of Reich (US 5,124,155). The Examiner alleged that while the instantly claimed invention differs from Tunc by further claiming that the wound dressing is in the form of a solid complex with collagen, Reich shows that dressings in the form of a solid complex with collagen are well known in the art. The Examiner further alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate collagen into the dressing comprising a sulfated hydroxyethyl cellulose of the Tunc patent, as evidenced by the Reich patent, because collagen exhibits beneficial effects in wound healing, such as by providing a matrix fro cell migration and growth.

Applicants respectfully disagree.

To establish a *prima fac*ie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all claim limitations. MPEP § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicants respectfully submit that the combination of Tunc and Reich does not teach, suggest, or otherwise disclose:

> "A wound dressing comprising a synthetic sulfated polysaccharide, wherein the sulfated polysaccharide is selected from the group consisting of sulfated hydroxyethyl cellulose, sulfated carboxymethyl cellulose and sulfated oxidized regenerated cellulose, ***said synthetic sulfated polysaccharide being present in an amount sufficient to bind matrix metalloproteinases***; and wherein at least one sulfate group on each saccharide residue of said synthetic sulfated polysaccharide was converted from a hydroxyl group" (emphasis added).

As noted above, Tunc does not teach, suggest, or otherwise disclose the limitation of at least one sulfate group on each saccharide residue of said synthetic sulfated polysaccharide was converted from a hydroxyl group – and indeed, teaches away from this limitation. Reich does not cure this deficiency. Reich does not teach any synthetic sulfated polysaccharides, let alone the degree of sulfate substitution, and therefore Reich does not overcome the deficiencies of Tunc. Thus, for the same reasons as stated above, the combination of cited references does not disclose all of the limitations of the applicants' claim 17.

As neither Tunc nor Reich discloses a wound dressing comprising a synthetic sulfated polysaccharide, said synthetic sulfated polysaccharide being present in an amount sufficient to bind matrix metalloproteinases, and wherein at least one sulfate group on each saccharide residue of said synthetic sulfated polysaccharide was converted from a hydroxyl group, the combination does not suggest, much less teach, the present invention. Consequently, applicants respectfully request withdrawal of the rejection of claim 17 under 35 U.S.C. § 103(a). Further, applicants submit that claims 9-10 and 18-22 are thereby allowable as written as depending from an allowable independent claim.

VIA ELECTRONIC FILING

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5025) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

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